Maryland Board of Pharmacy
Public Board Meeting

Agenda
November 18, 2020

Name	Title	Present	Absent
Ashby, D.	**Commissioner**		
Bouyoukas, E	**Commissioner**		
Evans, K.	**Commissioner**		
Fink, K.	**Commissioner**		
Hardesty, J.	**Commissioner/Treasurer**		
Geigher, P.	**Commissioner**		
Leikach, N.	**Commissioner**		
Morgan, K.	**Commissioner/President**		
Oliver, B	**Commissioner**		
Rusinko, K.	**Commissioner/Secretary**		
Singal, S.	**Commissioner**		
Yankellow, E.	**Commissioner**		
Bethman, L.	**Board Counsel**		
Felter, B.	**Board Counsel**		
Speights-Napata, D.	**Executive Director**		
Fields, E.	**Deputy Director /Operations**		
James, D.	**Licensing Manager**		
Leak, T.	**Compliance Director**		
Clark, B.	**Legislative Liaison**		
Chew, C.	**Management Associate**		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	**A.) K. Morgan, Board President** **B.)K. Rusinko, Secretary**	*Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.* **1. Call to Order** **2. Sign-in Introduction and of meeting attendees** – *(Please indicate on sign-in sheet if you are requesting CE Units for attendance)* **3. Distribution of Agenda and packet materials** **4. Review and approve October 2020 Public Meeting Minutes**	
II. A. Executive Director Report	**D. Speights-Napata, Executive Director**	**1. COVID-19 Update** **2. Staffing Update**	
B. New Business	**K. Morgan, Board President**	**1. None**	
C. Operations	**E. Fields, Deputy Director/ Operations**	**1. Procurement and Budget Updates** **a: October 2020 Financial Statements** **2. Management Information Systems (MIS) Unit Updates** **a: Systems Automation Purchase order effective 12/1/20 for Licensing program is approved**	
D. Licensing	**K. Rusinko**	**1. Unit Updates** **2. Monthly Statistics**	

License Type		New	Renewed	Reinstated	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)

			Distributor		**8**	**0**	**0**	**1,435**	
			Pharmacy		**17**	**1**	**0**	**2,096**	
			Pharmacist		**51**	**484**	**0**	**12,956**	
			Vaccination		**44**	**168**	**0**	**5,016**	
			Pharmacy Intern - Graduate		**0**	**0**	**0**	**61**	
			Pharmacy Intern - Student		**20**	**11**	**0**	**770**	
			Pharmacy Technician		**93**	**281**	**4**	**10,721**	
			Pharmacy Technician-Student		**0**	**0**	**0**	**29**	
			TOTAL		**233**	**945**	**4**	**33,084**	
E. Compliance	**T. Leak, Compliance Director**	**1. Unit Updates** **2. Monthly Statistics** **Complaints & Investigations:** New Complaints – 30							

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		• Medication Error – 3 • Fraud – 2 • Arrested for possession of firearms – 1 • Employee Pilferage – 2 • Disciplinary Action in Another State – 4 • Unprofessional Conduct – 3 • Dispensing Error – 1 • Refusal to Fill – 4 • Failure to Report Adverse Event – 3 • Inspection Issues – 6 • Unlicensed Personnel – 1 Resolved (Including Carryover) – 28 Actions within Goal –23/28 Final disciplinary actions taken – 3 Summary Actions Taken – 1 Average days to complete –63 **Inspections:** Total - 192 Annual Inspections - 115 Follow Up Narcotic Audit- 63 Opening Inspections - 13 Closing Inspections - 1 Relocation/Change of Ownership Inspections - 0 Board Special Investigation Inspections – 0	
F. Legislation & Regulations	**B. Clark, Legislative Liaison**	**<u>Regulations</u>** None	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Legislation None	
III. Committee Reports **A. Practice Committee**	**Evans, K. Commissioner**	**Anna Gribble** Maryland Department of Health: Could the Board of Pharmacy, or the Board's Executive Committee, consider requiring pharmacists to obtain the identification of individuals picking up a monitored prescription at the time of dispense? The PDMP currently collects information on the patient to whom the prescription was written, and the patient may not always be the person filling a prescription. The PDMP has a mechanism to collect this additional identification data, but we would like to coordinate with the Board of Pharmacy to assess the feasibility of pharmacies to obtain and report this information to the PDMP. This request is in response to a recommendation in the PDMP Sunset Evaluation: "Recommendation 8: PDMP should work with the State Board of Pharmacy to determine the feasibility of gathering information on the identification of the individual picking up a monitored prescription at the time it is dispensed" **Proposed Response:** The Board does not favor adding this to the mandatory reporting fields at this time, as it would be difficult to operationalize and require capital investment from individual pharmacies and software providers. Amos Chery Children's National Hospital: What is the Board of Pharmacy's position on remote order verification? Committee request for additional information/clarification of remote order verification.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Response from requestor - My question pertains to the location of a pharmacist that is verifying outpatient and inpatient orders. Can a pharmacist that is located in a different state verify orders for a Maryland-based pharmacy? In other words, is there any restrictions on the physical location of the pharmacist verifying orders before being administered by a nurse? **Proposed Response:** Remote order verification is considered the practice of pharmacy in Maryland; therefore, an out-of-state pharmacist engaged in remote order verification may do so in one of two ways: 1) may perform as an employee of a Board-permitted nonresident pharmacy (please note that non-resident pharmacy must have at least one Maryland-licensed pharmacist on staff) or 2) if the pharmacist is not working at a Maryland-permitted pharmacy, then the pharmacist *must* hold a Maryland pharmacist license to perform remote order verification. Lisa K. Shelton, Polaris Pharmacy Services: Can a nursing home administer flu vaccine to residents from a multi-dose vial pursuant to individual flu orders per patient? **Proposed Response:** Yes, nursing home pharmacists may administer from a multi-dose vial provided that all applicable laws, regulations, and standards are adhered to. **Shamika L Mazyck, Quarles & Brady LLP:** **Original Question**: Could you please tell me whether a wholesaler may deliver prescription drugs and devices to a medical doctor at a non-practice location? For example, a traveling physician may prefer to have Rx drugs and devices shipped to his or her home. Can they have drugs and devices shipped to a location that is not a clinic?	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Response from Board: Pursuant to Md. Code Ann., Health Occ. § 12-6C-09(c)(1), a distributor may only deliver prescription drugs to the premises listed on the recipient's license or permit. **Follow Up Question:** Can you share how a wholesale distributor should comply with the regulations below? Whom and how should the reporting take place? (f) A procedure for identifying, segregating, investigating, and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory *and reporting of such discrepancies within 5 business days to the Board* and appropriate federal or State agency upon discovery of such discrepancies. Md. Code Regs. 10.34.22.07(B)(f) **Response from Board:** Criminal Law Article, Section 5-303 requires Maryland-licensed distributors of CDS to report suspicious orders of CDS to both the Maryland Department of Health and the Maryland Office of the Attorney General. Please see the Department of Health's website for more information regarding how to submit suspicious order reports. (https://health.maryland.gov/ocsa/Documents/Suspicious%20Order%20Reporting%20Requirement.pdf [health.maryland.gov]). Wendy Tsang-Student: My preceptor had come across some information in Health Occupations 12-512: Single Dispensing from the Maryland Board of Pharmacy and was wondering if someone could help clarify some details? I have outlined her questions below.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		1. For Section (b)(2)- When it states a pharmacist "**cannot**" dispense a 90- day supply of a prescription order, does this pertain to the **first prescription of a drug** (meaning the pharmacy has never previously filled that medication for the patient) **OR** is it referring to the **first dispense of a new prescription** (meaning 90 days may be dispensed only if it is for a refill of that prescription)? 2. A pharmacist **cannot** dispense a 90-day supply of a prescription order if there is a change made to a prescription that has already been dispensed. Does this mean changes cannot be made to subsequent refills? 3. Lastly, does the "single dispense" of a quantity result in a loss or void of any remaining refills after the initial 90-day dispense? **Proposed Response:** 1. Your first interpretation—that 12-512 applies only to the first prescription of a drug to the patient—is the accurate interpretation of the statute. 2. A prescription can be changed as you have described, however, any change in drugs or dosage would make the prescription ineligible for a 90-day dispensing, as a prescription changing the dosage or drug would be considered the "first" prescription *at that dose* or of that drug. 3. No, this would not void the remaining refills. John Long: CVS Health: I am writing to you in my capacity as Pharmacy Regulatory Affairs Director for CVS Health and its family of pharmacies located across the country. CVS Health would like to thank the Maryland Board of Pharmacy for their constant vigilance to continuously improve regulations that enhance patient care and guide the practice of pharmacy in Maryland. Through our integrated offerings across the spectrum of pharmacy care, we are uniquely positioned to provide greater access to care, engage plan members in	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		behaviors that improve their health, and lower overall costs for health plans and their members. CVS Health provides multiple points of care to patients via our retail, mail, infusion, long- term-care, specialty pharmacies and Minute Clinics. I would like to obtain feedback from the Board Practice Committee regarding prescription processing. Can a pharmacist take an original oral prescription by a voice messaging system or by phone and directly enter into a data processing system the prescription information? If this is acceptable, would a printed hard copy prescription be required for recordkeeping? **Proposed Response:** Pursuant to COMAR 10.34.20.02(c), when a pharmacist takes a prescription orally, the pharmacist must reduce the oral prescription *to writing*. This provides a reference point for the data entered into the pharmacy's system. The data entry itself does not constitute a "writing" as it pertains to COMAR 10.34.20.02. Jody Fenelon: Partners Pharmacy: We have a potential customer that would like to use our remote automated medication dispensing system in their Free-Standing Urgent Care Facilities that is being planned in Maryland. I have reviewed the pharmacy and department of health licensing regulations and it is appears that this type of care setting may not be part of the currently approved Board of Pharmacy guidance for remote automated medication systems. But I wanted to confirm that with you. Also, if not currently permissible, what is the process with the Maryland Board of Pharmacy to present a request for a waiver or pilot that would allow for use in Free-Standing Urgent Care Facility? **Proposed Response:** 1. A pharmacy is only permitted to operate a remote automated medication dispensing system in a "related institution" per Md. Code Ann., Health Occ. §12-605. Unless the Urgent Care facilities	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		referenced in your question meet this definition, then the practice you have described would not be permissible. 2. There are currently no laws or regulations allowing the board to issue a waiver or greenlight a pilot program. Keyonia Green: I wanted to inquire about whose responsibility is it to clean/sanitize medicine packaging and dispensing machines. I work for a long- term care pharmacy who use packaging & dispensing machines to package and seal blisters. Almost daily tablets, capsules and caplets get stuck in the machine and contaminate the packaging material and other medicine. We as technicians are given alcohol to wipe the surface area of the machine but we are not provided with anything to sanitize the inside of the machines. I would greatly appreciate a response detailing the proper protocol for correcting this situation. **Proposed Response:** Under Md. Code Ann., Health Occ. § 12-403(c) (11), the pharmacy permit holder is responsible for maintaining the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
B. Licensing Committee	**K. Rusinko**	**1. Review of Pharmacist Applications:** **a. #123629 -** Applicant is requesting the Board grant her an extension of the Board's application and another extension of the NAPLEX score. At the August 2020 Board meeting an extension of NAPLEX score was granted until October 29, 2020. ***Committee recommendation: Approve score until May 31, 2021, must reapply*** **b. #119218 -** Applicant is requesting an extension of her NAPLEX ATT. Although her exam was initially scheduled in April, due to COVID 19 it was cancelled numerous times. ***Committee recommendation: Extend ATT eligibility for 6 months, must reapply*** **c. #120706 -** Applicant is requesting an extension of her MPJE ATT eligibility. In June 2020 the Board approved her request for an extension of her NAPLEX. Her NAPLEX extension expires 03/31/2021. ***Committee recommendation: Extend ATT eligibility until 03/31/2021, must reapply*** **d. #123611 -** Applicant is requesting an extension for his MPJE ATT Eligibility. Due to cancellations of testing caused by COVID 19. ***Committee recommendation: Approve a 6-month extension, must reapply*** **e. #127452 -** Applicant is requesting an extension of her NAPLEX score which expires 12/30/2020. She has been unable to take the MPJE due to the closing of the test centers.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Committee recommendation: Approve extension until 05/31/2021 **f. #124165 -** Applicant is requesting another attempt to take the MPJE. There have been 9 attempts, the last being 07/2020. In December 2019 the Board approved her request for the 9th attempt for the MPJE and extended her NAPLEX score until 07/25/2020. ***Committee recommendation: Approve for 6 months, must reapply if application expires.*** **g. #122245 -** Applicant is requesting an extension of her MPJE ATT eligibility. She was not allowed to take the exam prior to her authorizations expiration due to inconsistencies with her ID. ***Committee recommendation: Approve extension for 6 months, must reapply*** **h. #123906 -** Applicant is requesting the Board provide an extension to her Board application so that she may prepare and take the MPJE. ***Committee recommendation: Deny, must reapply.*** **i. #125342 -** Applicant is requesting the Board extend the expiration of her NAPLEX score, which expired 07/19/2020. ***Committee recommendation: Approve, 6-month extension from exam expiration date (July 2020)*** **j. #127273 -** Reciprocating pharmacist is requesting the Board approve her License Transfer application. NABP will not allow her to proceed with the License Transfer application without the FPGEC.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Although she graduated from a Pharmacy School in Ethiopia, she also attended Shenandoah University. ***Committee recommendation: Accept Shenandoah schooling and allow in order to reciprocate*** **k.** **#125747 -** Application is requesting a waiver of the wait tine to retake the MPJE. ***Committee recommendation: Deny*** **l.** **#123541 -** Applicant is requesting an extension of her Board application, which expired 10/18/2020. She made the request for extension. ***Committee recommendation: Deny, must reapply. Extend MPJE score until 05/31/2021*** **m.** **#124427 -** Applicant is requesting approval to retake the MPJE for a ninth attempt. ***Committee recommendation: Approve*** **n.** **#120818 -** Applicant is requesting an extension of her MPJE score until the end of February 2021. ***Committee recommendation: Approve extension, must reapply*** **o.** **#122292 -** Applicant is requesting an extension of his NAPLEX score. His score expired 09/12/2020. ***Committee recommendation: Approve extension until 05/31/2021, must reapply*** **2. Review of Pharmacy Intern Applications: NONE** **3. Review of Pharmacy Technician Applications:**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		a. #127435 - The applicant is requesting his application and documents from 1988-2004 be approved. The applicant received his Bachelor of Science (Education) degree Nigeria in 1988. He completed technician continuing education courses at Howard Community College from 1992-19994. In August 2004 he completed 50 class hours of technician training through Montgomery College. During 2002-2010 the applicant worked 40 hours a week in the role of a pharmacy technician at a Pharmacy. ***Committee recommendation: Approve*** **4. Review of Student Technician Applications:** **a. MZ (MZ 1, MZ 2) -** Student Technician is requesting approval to act as a Student Technician for another year, as his first year was deferred due to health reasons. ***Committee recommendation: Approve for Additional year*** **5. Review of Distributor Applications: NONE** **6. Review of Pharmacy Applications: NONE** **7. Review of Pharmacy Technicians Training Programs:** **a. Precise Pharmacy Technician Training** ***Committee recommendation: Approve*** **8. CE Requests** **a. MBF (MBF SUDS 1, MBF SUDS 2, MBF SUDS 3, MBF SUDS 4)-** 2020 Substance Use Disorder Annual Symposium WRNMM	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Committee recommendation: Approve 5.75 hours **b. ODA** - 2020 Substance Use Disorder Annual Symposium WRNMMC ***Committee recommendation: Approve 2.25 hours*** **9. New Business:** **a. QPharma** - Company is requesting guidance regarding providing prescription drug samples directly to patients. Due to COVID 19, samples cannot be provided by physicians to the patients. ***Committee recommendation: If the requirements of the FDA guidance can be met, then it is acceptable to do so.*** **b. Professional Care Pharmacy (PCP DRP)** - The Compliance Unit is requesting review of the permit issued to confirm if the facility can have a Repository on site. ***Committee recommendation: In order to be a repository that accepts controlled substances, the facility must register with the DEA and meet DEA requirements before the Board can schedule the inspection and approve the repository application.*** **c. Collaborative Practice Agreements** - If a pharmacist does not meet the criteria of COMAR 10.34.29.04 A (4) (a) and has not completed a residency accredited by ASHP, what training programs/examinations approved by the Board that would make the pharmacist eligible to participate in a collaborative practice agreement?	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Committee recommendation: The Board reviews on a case-by-case basis. Please provide a course/examination for the Board to review. **d. CH -** Pharmacist will be reciprocating to Maryland, she is requesting the Board accepts the hours she has worked as a pharmacist at a professional association to meet the 520 hours' requirement to reciprocate. ***Committee recommendation: Approve*** **e. BA -** Reciprocating Pharmacist is requesting the Board waive the FPGEC requirement. ***Committee recommendation: Deny*** **f. AA -** Registrant is requesting an extension of his Intern-Graduate registration to allow him to finish his exams. ***Committee recommendation: Extend until 07/31/2021*** **g. BDH Consulting LLC -** Is a permit required for a virtual pharma company that owns NDA/ANDAs but will not be distributing the products? They will have a distribution partner (another pharmaceutical company with that company's name on the product label) that will distribute. ***Committee recommendation: Permit needed, company qualifies for use of the abbreviated form.*** **h. Bonnie Scott -** Writing to confirm whether Maryland's permit requirement for Manufacturers and Virtual Manufacturers Distributing Their Own Prescription Drugs and Devices would apply to an out-of-state contract drug manufacturer that does not directly distribute any products into Maryland	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		("Company A"). Company A contract manufactures drugs on behalf of pharmaceutical company customers that pick up such products from its out-of-state facilities. Company A's customers may go on to distribute those products in Maryland, but Company A is not involved in those activities. Company A holds FDA marketing authorizations for certain of the drugs it sells to customers (in those cases, it private labels products for its customers), but for other drugs, Company A's customers are the FDA marketing authorization holders. Based on these facts, and my review of the relevant laws and guidance, it appears that neither the permit requirement for Manufacturers and Virtual Manufacturers Distributing Their Own Prescription Drugs and Devices nor the permit requirement for Wholesale Distributors would apply to Company A. Can you please confirm? ***Committee recommendation: Company A would not require a permit, Company B requires a permit***	
C. Public Relations Committee	**E. Yankellow, Chair**	**Public Relations Committee Update:**	
D. Disciplinary	**J. Hardesty, Chair**	**Disciplinary Committee Update**	
E. Emergency Preparedness Task Force	**N. Leikach, Chair**	**Emergency Preparedness Task Force Update**	
IV. Other Business & FYI	**K. Morgan, President**		
V. Adjournment	**K. Morgan, President**	**A. The Public Meeting was adjourned.**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		B. K. Morgan convened a Closed Public Session to conduct a medical review committee evaluation of confidential applications. **C. The Closed Public Session was adjourned. Immediately thereafter, K. Morgan convened an Administrative Session for purposes of discussing confidential disciplinary cases.** **D. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Closed Public Session and the Administrative Session.**	